TITLE 175 HEALTH CARE FACILITIES AND SERVICES LICENSURE

CHAPTER 8 PHARMACIES

Note: In these draft regulations, proposed fee changes are found on page 12. Technical and editing changes are made throughout the chapter. Other proposed changes will revise or add regulations on:

- **Definitions, pages 3-4**
- **Renewals, page 9**
- **Required notice to the Department, page 12**
- **Inspections, pages 18-19**
- **Controlled substance disposal, page 30**
- **Disaster preparedness, pages 31-32**

8-001 SCOPE AND AUTHORITY: These regulations govern licensure of Pharmacies. The regulations are authorized by and implement the Health Care Facility Licensure Act, Neb. Rev. Stat. §§ 71-401 to 71-459.

8-002 DEFINITIONS

Administer means to directly apply a drug or device by injection, inhalation, ingestion, or other means to the body of a patient or research subject.

Administration means the act of:

1. administering;
2. keeping a record of the activity; and
3. observing, monitoring, reporting, and otherwise taking appropriate action regarding desired effect, side effect, interaction, and contraindication associated with administering the drug or device.

Agent means an authorized person who acts on behalf of or at the direction of another person but does not include a common or contract carrier, public warehouse keeper, or employee of a carrier or warehouse keeper.

Applicant means the individual, government, corporation, partnership, limited liability company or other form of business organization who applies for a license.

Biological or biological product means any virus, therapeutic serum, toxin, antitoxin or analogous product applicable to the prevention, treatment or cure of disease or injuries of humans.

Board means the Board of Pharmacy.

Caregiver means any person acting as an agent on behalf of a patient or any person aiding and assisting a patient.

Central fill means the preparation, other than by compounding, of a drug, device or biological pursuant to a medical order where the preparation occurs in a pharmacy other than the pharmacy dispensing to the patient or caregiver.

Chart order means an order for a drug or device issued by a practitioner for a patient who is in the hospital where the chart is stored or for a patient receiving detoxification treatment or maintenance treatment pursuant to Neb. Rev. Stat. § 28-412. Chart order does not include a prescription.

Complaint means an expression of a concern or dissatisfaction.

Completed application means the application that contains all the information specified in 175 NAC 8-003 and includes all required attachments and documentation and the licensure fee.

Compounding means the preparation of components into a drug product.

(a) As the result of a practitioner's medical order or initiative occurring in the course of practice based upon the relationship between the practitioner, patient, and pharmacist; or
(b) For the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing. Compounding includes the preparation of drugs or devices in anticipation of receiving medical orders based upon routine, regularly observed prescribing patterns.

D.E.A. means the Drug Enforcement Administration of the United States Department of Justice.

Department means the Department of Health and Human Services Regulation and Licensure.

Device means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is prescribed by a practitioner and dispensed by a pharmacist or other person authorized by law to do so.

Director means the Director of Regulation and Licensure.

Dispense or dispensing means interpreting, evaluating, and implementing a medical order, including preparing and delivering a drug or device to a patient or caregiver in a suitable container appropriately labeled for subsequent administration to, or use by, a patient. Dispensing includes:

1. Dispensing incident to practice;
2. Dispensing pursuant to a delegated dispensing permit;
3. Dispensing pursuant to a medical order; and
4. Any transfer of a prescription drug or device to a patient or caregiver other than by administering.

Distribute means to deliver a drug or device, other than by administering or dispensing.

Drug means substances as defined in Neb. Rev. Stat. § 71-1,142.

Grievance means a written expression of dissatisfaction, which may or may not be the result of an unresolved complaint.

Healing arts means a health profession in which a licensed practitioner offers or undertakes to diagnose, treat, operate on, or prescribe for any human pain, injury, disease, deformity, or physical or mental condition.

Health care practitioner means any individual credentialed under the Uniform Licensing Law or other laws of the State of Nebraska.

Labeling means the process of preparing and affixing a label to any drug container or device container, exclusive of the labeling by a manufacturer, packer, or distributor of a nonprescription drug or commercially packaged legend drug or device. Any such label must include all information required by federal and state law or regulation.

Licensee means the individual, government, corporation, partnership, limited liability company or other form of business organization legally responsible for the operation of the facility and to whom the Department has issued a license.

Long-term care facility means a nursing facility, skilled nursing facility, intermediate care facility, intermediate care facility for persons with mental retardation, or long-term care hospital, but not an assisted-living facility.

Medical order means a prescription, or chart order, or an order for pharmaceutical care issued by a practitioner.

NAC means Nebraska Administrative Code.

Patient counseling means the verbal communication by a pharmacist, pharmacist intern, or practitioner, in a manner reflecting dignity and the right of the patient to a reasonable degree of privacy, of information to the patient or caregiver in order to improve therapeutic outcomes by maximizing proper use of prescription drugs and devices and also includes the duties set out in Neb. Rev. Stat. § 71-1,147.35.

Person means an individual, corporation, partnership, limited liability company, association, or other legal entity.

Pharmaceutical care means the provision of drug therapy for the purpose of achieving therapeutic outcomes that improve a patient's quality of life. Such outcomes include:

1. the cure of disease,
2. the elimination or reduction of a patient's symptomatology,
3. the arrest or slowing of a disease process, or
4. the prevention of a disease or symptomatology.

Pharmaceutical care includes the process through which the pharmacist works in concert with the patient and his/her caregiver, physician, or other professionals in designing, implementing, and monitoring a therapeutic plan that will produce specific therapeutic outcomes for the patient.

Pharmacist means any person who is licensed by the State of Nebraska to practice pharmacy.

Pharmacist-in-charge means a pharmacist who is designated on a pharmacy license or designated by a hospital as being responsible for the practice of pharmacy in the pharmacy for which a pharmacy license is issued and who works within the physical confines of the pharmacy for a majority of the hours per week that the pharmacy is open for business averaged over a 12-month period or 30 hours per week, whichever is less.

Pharmacy means a facility where drugs or devices are dispensed.

Pharmacist intern means

1. A student currently enrolled in an accredited ~~college or school of~~ pharmacy program or
2. A graduate of an accredited ~~college or school of~~ pharmacy program serving his/her internship, the internship to expire not later than 15 months after the date of graduation or at the time of professional licensure, whichever comes first.

Such pharmacist intern may compound and dispense drugs or devices and fill prescriptions only in the presence of and under the immediate personal supervision of a licensed pharmacist. Such licensed pharmacist must either be:

a. The person to whom the pharmacy license is issued or a person in the actual employ of the pharmacy licensee or
b. The delegating pharmacist designated in a delegated dispensing agreement by a hospital with a delegated dispensing permit.

Pharmacy technician means an individual at least 18 years of age who is a high school graduate or officially recognized by the State Department of Education as possessing the equivalent degree of education, who has never been convicted of any drug-related misdemeanor or felony, and who, under the written control procedures and guidelines of an employing pharmacy, may perform those functions which do not require professional judgment and which are subject to verification to assist a pharmacist in the practice of pharmacy.

Practice of Pharmacy means the

1. Interpretation, evaluation, and implementation of a medical order;
2. The dispensing of drugs and devices;
3. Drug product selection;
4. The administration of drugs or devices;
5. Drug utilization review;
6. Patient counseling;
7. Provision of pharmaceutical care, and

8. Responsibility for compounding and labeling of dispensed or repackaged drugs and devices, proper and safe storage of drugs and devices, and maintenance of proper records.

Practitioner means an advanced practice registered nurse, certified registered nurse anesthetist, certified nurse midwife, dentist, optometrist, physician assistant, physician, podiatrist, or veterinarian.

Premises means a facility, the facility's grounds and each building or grounds on contiguous property used for administering and operating a facility.

Prescription drug or device or legend drug or device means:

1. A drug or device which is required under federal law, to be labeled with one of the following statements prior to being dispensed or delivered:

   a. Caution: Federal law prohibits dispensing without prescription; or
   b. Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian; or
   c. Rx Only.

2. A drug or device which is required by any applicable federal or state law to be dispensed pursuant only to a prescription or which is restricted to use by practitioners only.

Prescription means an order for a drug or device issued by a practitioner for a specific patient, for emergency use, or for use in immunizations. Prescription does not include a chart order.

Signature means the name, word, or mark of a person written in his/her own hand with the intent to authenticate a writing or other form of communication or a digital signature which complies with Neb. Rev. Stat. § 86-611 or an electronic signature.

Supervision means the immediate personal guidance and direction by the licensed pharmacist on duty in the facility of the performance by a pharmacy technician of authorized activities or functions subject to verification by the pharmacist, except that when a pharmacy technician performs authorized activities or functions to assist a pharmacist on duty in the facility when the prescribed drugs or devices will be administered by a licensed staff member or consultant or by a licensed physician assistant to persons who are patients or residents of a facility, the activities or functions of the pharmacy technician are only subject to verification by a pharmacist on duty in the facility.

Verification means the confirmation by a supervising pharmacist of the accuracy and completeness of the acts, tasks, or functions undertaken by a pharmacy technician to assist the pharmacist in the practice of pharmacy.

Written control procedures and guidelines means the document prepared and signed by the pharmacist-in-charge and approved by the Board which specifies the manner in which basic levels of competency of pharmacy technicians employed by the pharmacy are determined, the

manner in which supervision is provided, the manner in which the functions of pharmacy technicians are verified, the maximum ratio of pharmacy technicians to one pharmacist used in the pharmacy, and guidelines governing the use of pharmacy technicians and the functions which they may perform.

8-003 LICENSING REQUIREMENTS AND PROCEDURES: Any person, including a practitioner, intending to establish, operate, or maintain a pharmacy must first obtain a license from the Department. A pharmacy must not hold itself out as a pharmacy or as providing health care services unless licensed under the Health Care Facility Licensure Act. An applicant for an initial or renewal license must demonstrate that the pharmacy meets the operational and physical plant standards contained in 175 NAC 8.

8-003.01 Application Process for Initial Licensure

8-003.01A Applicant Responsibilities: No person may operate a pharmacy until the Department has issued either a provisional pharmacy license or a pharmacy license for that pharmacy. An applicant for an initial pharmacy license must:

1. Intend to provide pharmacy services as stated in the application;
2. Comply with the applicable standards specified in 175 NAC 8-006 and 8-007;
3. Submit a signed application verifying that all information in the application is correct. The application must contain the following:

    a. Pharmacy or practitioner name,
    b. Pharmacy or practitioner street address,
    c. Pharmacy or practitioner telephone number,
    d. Name of owner(s), partners, or corporation,
    e. If a corporation, name of corporate officers,
    f. Mailing address(es) of owner(s), partners, or corporation,
    g. Anticipated opening date,
    h. Anticipated days and hours pharmacy will be open for business,
    i. Name of pharmacist-in-charge or name of practitioner,
    j. Nebraska license number of pharmacist-in-charge or Nebraska license number of practitioner,
    k. Expiration date of the license of the pharmacist-in-charge or expiration date of practitioner's license,
    l. If controlled substances are to be dispensed, the D.E.A. registration number or proof that an application is in process,
    m. A description of how the pharmacy meets the following requirements:

        (1) The prescription inventory and prescription records of the pharmacy must be maintained in a secure location when there is no pharmacist on the premises.
        (2) The pharmacy must store drugs, devices, and biologicals at the proper temperature.

(3) The pharmacy must not have in its saleable inventory any drug, device, or biological which is misbranded or adulterated.

(4) The pharmacy must provide the pharmacist access to all equipment appropriate for the accurate, efficient, and safe provision of the services available in that pharmacy. List all services intended to be provided by the pharmacy.

(a) Examples of services which may be provided by a pharmacy include, but are not limited to: ambulatory dispensing, unit-dose dispensing, sterile compounding, non-sterile compounding, and administration of vaccinations or injections.

(5) The pharmacy must provide the pharmacist access to all facilities appropriate for the accurate, efficient, and safe provision of the services available in that pharmacy.

(6) The pharmacy must provide the pharmacist access to all utilities appropriate for the accurate, efficient, and safe provision of the services available in that pharmacy.

(7) The pharmacy must provide the pharmacist access to all reference material appropriate for the accurate, efficient, and safe provision of the services available in that pharmacy. These references must be current, in either printed or electronic form, and available at all times while the pharmacist is practicing for that pharmacy. List the references to be used in the pharmacy; and

4. Submit the required fee as specified in 175 NAC 8-004.11.

8-003.01B Department Process for Initial Licensure: The initial license process occurs in two stages. The application is not complete until the Department receives the documents specified in 175 NAC 8-003.01A3.

8-003.01B1 Provisional Pharmacy License: The first stage consists of the Department conducting an opening inspection according to 175 NAC 8-005.01 to determine the applicant's ability to comply with the operational and physical plant standards contained in 175 NAC 8-006 and 8-007. The Department will:

1. Review the application for completeness as part of the opening inspection in accordance with 175 NAC 8-005.01;
2. Provide notification to the applicant of any information needed to complete the application;
3. Issue a provisional pharmacy license if the Department determines that the pharmacy has substantially complied but fails to fully comply with the requirements for licensure under the Act and that the failure does not pose an imminent danger of death or

physical harm to the persons served by the pharmacy. The provisional license:

a. Is valid for up to one year;
b. Is not renewable; and
c. May be converted to a regular license upon a showing that the pharmacy has fully complied with the requirements for licensure; or

4. Deny the provisional pharmacy license if the Department determines that the pharmacy fails to fully comply with the requirements for licensure under the Act and that the failure poses an imminent danger of death or physical harm to the persons served by the pharmacy.

8-003.01B2 Pharmacy License: The second stage consists of the Department's initial on-site inspection of the pharmacy in accordance with 175 NAC 8-005.02. The Department determines whether or not the applicant for a pharmacy license fully meets the standards contained in 175 NAC 8 and the Health Care Facility Licensure Act. The Department will:

1. Conduct an initial on-site inspection in accordance with 175 NAC 8-005.02 within 60 days after the issuance of the provisional pharmacy license;
2. Provide notification to the applicant of the results of the initial on-site inspection within 10 days after the completion of the inspection, in accordance with 175 NAC 8-005.02;
3. Issue a pharmacy license based on the results of the initial on-site inspection if the Department determines that the pharmacy has fully complied with the requirements for licensure under the Act;
4. Issue a pharmacy license based on the results of the initial on-site inspection if the Department determines that the pharmacy has substantially complied but fails to fully comply with the requirements for licensure under the Act and that the failure does not pose an imminent danger of death or physical harm to the persons served by the pharmacy; and/or
5. Deny the pharmacy license if the Department determines that the pharmacy fails to fully comply with the requirements for licensure under the Act and that the failure poses an imminent danger of death or physical harm to the persons served by the pharmacy.

8-003.01C Denial of License: The Department may deny a pharmacy license when an applicant fails to meet the requirements for licensure, including:

1. Failing an inspection;
2. Failing to meet a compliance assessment standard;
3. Having had a license revoked within the two-year period preceding application; or

4. Any of the grounds listed in 175 NAC 8-008.01B.

8-003.02 Renewal Licenses

8-003.02A Department Responsibilities: The Department will:

1. Send a notice of expiration and an application for renewal to the applicant's preferred mailing address no later than 30 days prior to the expiration date. The license renewal notice specifies:

   a. Date of expiration;
   b. Fee for renewal;
   c. License number; and
   d. Name and address of the pharmacy.~~; and~~
   ~~e. A request for documentation pertaining to the pharmacy's Federal Controlled Substances Registration.~~

2. Issue a renewal when it determines that the applicant has submitted a completed application;

3. Send to each licensee that fails to renew its license a second notice, which is the final notice and specifies that:

   a. The licensee failed to pay the renewal fee or submit an application or both;
   b. The license has expired;
   c. The Department will suspend action for 30 days following the date of expiration;
   d. Upon receipt of the renewal fee and completed renewal application, the Department will issue the renewal license; and
   e. That upon failure to receive the renewal fee and completed renewal application, the license will be lapsed.

4. Place the pharmacy license on lapsed status for nonpayment of fees if the licensee fails to renew the license. During this time, the pharmacy may not operate. The license remains in lapsed status until it is reinstated.

8-003.02B Licensee Responsibilities: The licensee must submit:

1. The application for renewal;
2. Confirmation as requested by the Department ~~A copy~~ of the pharmacy's or practitioner's current D.E.A. Registration, if any;
3. The name of the pharmacist-in-charge or the practitioner; and
4. The required renewal fee as specified in 175 NAC 8-004.11.

8-003.02C Refusal to Renew: The Department may refuse renewal of a pharmacy license that fails to meet the requirements for renewal, including:

1. Failing an inspection;
2. Failing to meet a compliance assessment standard;
3. Having had a license revoked within the two-year period preceding application; or
4. Any of the grounds listed in 175 NAC 8-008.01B.

8-003.03 Reinstatement from Lapsed Status: A pharmacy requesting reinstatement of its lapsed license must submit to the Department an application for reinstatement and pay the required license fee specified in 175 NAC 8-004.11. The application must conform to the requirements specified in 175 NAC 8-003.02.

8-003.03A The Department will review the application for completeness and ~~must~~ will decide if an on-site inspection is needed to determine compliance with the operational and physical plant standards of 175 NAC 8-006 and 8-007. The decision is based on the following factors:

1. The length of time that has transpired from the date the license was placed on lapsed status to the date of the reinstatement application; and
2. Whether the pharmacy has provided pharmacy services from the site under a license that is different from the lapsed license.

8-003.03B When the Department decides that an on-site reinstatement inspection is warranted, it ~~must~~ will conduct the inspection in accordance with 175 NAC 8-005.02.

8-003.03C When the Department decides that an on-site reinstatement inspection is not warranted, it ~~must~~ will reinstate the license.

8-003.03D Refusal to Reinstate: The Department may refuse reinstatement of a pharmacy license that fails to meet the requirements for reinstatement, including:

1. Failing an on-site inspection;
2. Failing to meet a compliance assessment standard;
3. Having had a license revoked within the two-year period preceding application; or
4. Any of the grounds listed in 175 NAC 8-008.01B.

8-003.04 Permanently Closing a Pharmacy

8-003.04A When a pharmacy ceases legal existence, discontinues business or has a change of ownership, the pharmacist-in-charge or practitioner of that pharmacy must notify the Department within 15 days of closing.

8-003.04B The notice must include the following information:

1. The sale or other disposition of legend drug, device, or biological inventory,

2. The sale or other disposition of controlled substances and controlled substances invoices and inventory records, and
3. The location of all patient records including prescription files.

8-003.04C The pharmacist-in-charge or practitioner must return the following to the Department:

1. The pharmacy license,
2. The pharmacy's D.E.A. Registration, if any,
3. All unused D.E.A. Forms 222 for the pharmacy, if any, and
4. All unused D.E.A. Forms 222a or 222d for the pharmacy, if any.

8-003.04D When the closing of a pharmacy is anticipated, the pharmacist-in-charge or practitioner is responsible for notifying patients of that pharmacy that they will need to seek service elsewhere. The notification can be accomplished through:

1. Advertisement in a newspaper appropriate to the location of the pharmacy,
2. Written notice to patients of the pharmacy, or
3. Other such notice as is appropriate.

8-004 GENERAL REQUIREMENTS

8-004.01 License Usage: The licensee must not provide pharmacy services except those set out in their initial application for a pharmacy license or any amendment thereto.

8-004.02 Effective Date and Term of License: A pharmacy license expires on July 1 of each year.

8-004.03 License Not Transferable: A license is issued only for the premises and persons named in the application and is not transferable or assignable. Change of ownership (sale, whether of stock, title, or assets, lease, discontinuance of operations) or change of premises terminates the license. If there is a change of ownership and the pharmacy remains on the same premises, the inspection in 175 NAC 8-005 is not required. The new owner(s) must apply for a new pharmacy license. If there is a change of premises, the owner(s) must apply for a new pharmacy license and the pharmacy must pass the inspection specified in 175 NAC 8-005.

8-004.04 Notification: An applicant or licensee must notify the Department of any change as set forth in 175 NAC 8-004.05 through 8-004.10. The following information is required for all notifications:

1. Current name and license number of the pharmacy or practitioner;
2. Street address of pharmacy or practitioner;
3. Name of owner(s), partners, or corporation;
4. If a corporation the name of corporate officers;
5. Mailing address(es) of owner(s), partners, or corporation;
6. Reason for notifying the Department about a change in the existing license;

7. A ~~notarized,~~ signed statement from the applicant or licensee verifying that all information ~~in the application~~ is correct; and
8. The required fee as specified in 175 NAC 8-004.11, if any.

8-004.05 Change of Pharmacist-in-Charge: The licensee must notify the Department immediately when there is a change in the pharmacist-in-charge.

8-004.06 Change of Ownership or Premises ~~Location~~: The licensee must notify the Department in writing 30 days before a pharmacy is sold, leased, discontinued, or moves~~d~~ to ~~a~~ new premises. ~~location and may be subject to inspection as outlined in 175 NAC 8-005.06~~.

8-004.07 Change of Name of the Pharmacy: The licensee must notify the Department in writing within 5 working days when there is a change in the name of the pharmacy.

8-004.08 Continuation of a Pharmacy by the Heirs or Estate of a Deceased Licensee: The heirs or executor of the estate must notify the Department with 30 days of the death of the licensee.

8-004.09 Change of Services: The licensee must notify the Department of any change in the type or scope of services provided as listed on the application or amendments thereto.

8-004.10 An Accident, Natural Disaster, or Interruption in Utility Services: The licensee must notify the Department in writing by electronic mail, facsimile, or postal service within 24 hours of any change in environment which will adversely ~~e~~affect the potency, efficacy, safety or security of the drugs, devices or biologicals in the pharmacy.

8-004.11 Fees: The licensee must pay fees for licensure as follows:

8-004.11A The required fees are:

1. Initial pharmacy license fee is ~~$255~~ $625.
2. Annual pharmacy license renewal fee is ~~$255~~ $625.
3. Duplicate license fee is $10.

8-004.11B Refunds for denied applications

1. If the Department did not perform an initial on-site inspection, the license fee is refunded except for an administration fee of $25; or
2. If the Department performed an initial on-site inspection, the fee is not refunded.

8-005 ~~COMPLIANCE~~ INSPECTIONS: Each pharmacy has the responsibility to be in compliance, and to remain in compliance, with the regulations set out in this chapter. The Department has the responsibility to determine that the pharmacies are in compliance at all times. For the purpose of assuring initial and continued compliance, each pharmacy must prepare Pharmacy Quality Assurance Reports and the Department will conduct inspections as set out below:

8-005.01 Opening Inspection: The Department will conduct an opening inspection by a review of the application for a pharmacy license. The answers on this application will be reviewed for accuracy, completeness, and correctness by a pharmacy inspector. Because a pharmacy cannot be in full compliance with the operational and physical plant standards for a pharmacy as specified in 175 NAC 8-006 and 8-007 prior to the time the pharmacy has been in operation, the pharmacy inspector must provide a recommendation to the Department as to whether the application indicates substantial compliance with 175 NAC 8-003.01A item 3.m. in preparation for its opening, and whether the probability of full compliance exists when the pharmacy begins to operate.

8-005.01A Department Determination: The Department will make its determination based on the recommendation to issue or deny a pharmacy license.

8-005.01B Results of Opening Inspection

8-005.01B1 When the Department finds that the applicant substantially complies with 175 NAC 8-003.01A item 3.m. and that any failure does not pose an imminent danger of death or physical harm to the persons served by the pharmacy, the Department ~~must~~ will issue a provisional pharmacy license.

8-005.01B2 When the Department finds that the applicant fails to substantially comply with 175 NAC 8-003.01A item 3.m., the Department will deny a pharmacy license.

8-005.02 Initial On-site Inspection: After April 1, 2002, the Department will conduct an announced initial on-site inspection within 60 days of the issuance of a provisional pharmacy license. The inspection ~~must~~ will determine whether the pharmacy fully complies with the requirements for a pharmacy license. The pharmacist-in-charge must be present for the initial on-site inspection.

8-005.02A Department Determination: Such determination ~~must~~ will be made when the pharmacy inspector:

1. Verifies the operational and physical plant standards as described on the application for a pharmacy license are in place;
2. Verifies whether the written control procedures and guidelines for using pharmacy technicians have been submitted to the Department, when the pharmacy intends to use pharmacy technicians;
3. Verifies that an initial controlled substances inventory was taken, if the pharmacy intends to dispense controlled substances, and that the inventory is on file in the pharmacy on the date the pharmacy first engages in the distribution or dispensing of prescription drugs; and
4. Ensures that the Pharmacy Quality Assurance Report as described in 175 NAC 8-005.03 is understood by the pharmacist-in-charge and clarifies and discusses any areas that warrant attention.

8-005.02B Results of Initial On-site Inspection: The Department will review the findings of an initial on-site inspection within 20 working days after the inspection.

8-005.02B1 When the Department finds that the provisional licensee fully complies with the requirements of 175 NAC 8-003.01A item 3.m., 175 NAC 8-006 and 8-007, the Department will issue a pharmacy license.

8-005.02B2 When the Department finds that the provisional licensee does not fully comply with the requirements of 175 NAC 8-003.01A item 3.m., 175 NAC 8-006 and 8-007 but the nature of the violations do not create an imminent danger of death or serious physical harm to the patients of the pharmacy and no direct or immediate adverse effect to the safety or security of the drugs, devices, and biologicals, the Department may send to the pharmacy a letter requesting that a statement of compliance be submitted. The letter ~~must~~ will include:

1. A description of each violation;
2. A request that the pharmacy submit a statement of compliance within 10 working days; and
3. A notice that the Department may take further steps if the statement of compliance is not submitted.

8-005.02B3 The statement of compliance submitted by a pharmacy must indicate any steps that have been or will be taken to correct each violation and the estimated time to correct each violation. Based on the statement of compliance, the Department will take one of the following actions:

1. If the pharmacy submits and implements a statement of compliance that indicates a good faith effort to correct the violations, the Department may:

    a. Allow the pharmacy to continue practice under the provisional pharmacy license; or
    b. Issue a pharmacy license.

2. If the pharmacy fails to submit and implement a statement of compliance that indicates a good faith effort to correct the violations, the Department may:

    a. Deny a pharmacy license; and
    b. Initiate disciplinary action against the provisional pharmacy license.

8-005.02B4 When the Department finds the applicant fails to meet the requirements of 175 NAC 8-003.01A item 3.m., 175 NAC 8-006 and 8-007 and the failure(s) would create an imminent danger of death or serious physical harm, the Department will deny a pharmacy license and revoke the provisional pharmacy license.

8-005.03 Pharmacy Quality Assurance Report: All pharmacies must ensure that the pharmacist-in-charge annually submits a completed Pharmacy Quality Assurance Report on a form made available by the Department, electronically or upon request, within 30 days of the due date of the report, as specified in 175 NAC 8-005.03C.

8-005.03A This report must provide information on the following:

1. Adequate security;
2. Proper environmental controls;
3. Appropriate cleanliness and sanitation;
4. Reference requirements are met;
5. Poison control phone number is posted;
6. Required equipment is available;
7. A verbal offer to counsel the patient or the patient's caregiver is being made;
8. Documentation of refusal of patient counseling exists;
9. Only pharmacists or pharmacist interns are providing patient counseling;
10. Prospective drug utilization review is being conducted;
11. Record keeping requirements have been met;
12. Computer back up, if applicable, has been completed;
13. Outdated inventory is segregated from stock that is intended to be sold or dispensed and is stored in such a manner as to prevent it from being sold or dispensed;
14. Misbranded or adulterated inventory is segregated from stock that is intended to be sold or dispensed and is stored in such a manner as to prevent it from being sold or dispensed;
15. Unit-dose labels meet requirements, if applicable;
16. Controlled substances inventory records are complete and accurate;
17. A copy of the biennial inventory and other required inventories was sent to the Department, when applicable;
18. All D.E.A. Forms 222 are properly completed;
19. All controlled substance Schedule II invoices are properly maintained;
20. All controlled substance Schedule III-V invoices are properly maintained;
21. All controlled substances are properly stored;
22. All controlled substance transfers between registrants have been properly recorded;
23. Date of issuance is recorded on all prescriptions;
24. Date of initial filling on all prescriptions;
25. All prescriptions bear the name of the patient;
26. All controlled substance prescriptions contain the patient's address;
27. All prescriptions contain the name of the prescriber and if written, the prescriber's signature in indelible ink or indelible pencil and contain the name of the prescriber either stamped, typed or clearly handwritten;
28. All controlled substance prescriptions contain the prescriber's address,
29. All controlled substance prescriptions contain the D.E.A. number of the prescriber;

30. All prescriptions contain the name, strength and quantity of medication dispensed;
31. Compliance with refill requirements;
32. All prescriptions contain directions for use by the patient or caregiver;
33. Partial fillings are properly recorded and dispensed appropriately;
34. All dispensed prescriptions for a controlled substance Schedule II are signed and dated on the face of the written prescription by the pharmacist or pharmacist intern;
35. All emergency controlled substance Schedule II authorizations are properly recorded;
36. ~~Electromagnetic~~ Facsimile or electronic transmission requirements are followed;
37. All prescriptions are checked for correct interpretation and filling;
38. All prescription containers are properly labeled;
39. All inventory labels meet the requirements;
40. An original hard copy is on file for all controlled substance Schedule II prescriptions, except when otherwise allowed by the Uniform Controlled Substances Act;
41. Compliance with the Drug Product Selection Act;
42. All initial prescription fillings and refills are dated, initialed, and documented;
43. Proper prescription filing system is used and maintained;
44. Proper records for emergency drug boxes are maintained, if applicable,
45. Approved written control procedures and guidelines for the use of pharmacy technicians are followed;
46. Controlled substance Power-of-Attorney forms are complete and appropriately filed, if applicable; and
47. All information supplied on the application for a pharmacy license pursuant to 175 NAC 8-003.01A item 3.m. is complied with.

8-005.03B This report must be accompanied by a signed statement from the pharmacist-in-charge verifying that all information in the Pharmacy Quality Assurance Report is accurate, complete, correct, and in compliance with 175 NAC 8-003.01A item 3.m., 175 NAC 8-006 and 8-007.

8-005.03C The Pharmacy Quality Assurance Report is due one year from the date of the initial on-site inspection, and annually thereafter.

8-005.03D Department Responsibilities: The Department will review the Pharmacy Quality Assurance Report within 20 working days after the report is submitted to determine whether the pharmacy:

1. Is providing the services and is operating in a manner that is consistent with the information provided in the application for a pharmacy license and any amendments thereto.
2. Is being operated in compliance with the Health Care Facilities Licensure Act and these regulations.

8-005.04 Annual Inspection: After April 1, 2002, all pharmacies are subject to an annual inspection to determine whether a pharmacy fully complies with the requirements of 175 NAC 8-003.01A item 3.m., 175 NAC 8-006 and 8-007. The inspection may occur by a self-inspection or by an on-site inspection.

8-005.04A Self-Inspection: The Pharmacy Quality Assurance Report ~~must~~ will fulfill the annual inspection requirement when the Department determines that the report indicates that the pharmacy is in full compliance with the Health Care Facilities Licensure Act and these regulations. However, the report will not fulfill the annual inspection requirement when:

1. The Department has determined, based on the review of the Pharmacy Quality Assurance Report, that the pharmacy is not in compliance with the Health Care Facilities Licensure Act or these regulations;
2. The pharmacy failed to be in full compliance with the regulations at the time of its last inspection;
3. The pharmacy failed to submit a Pharmacy Quality Assurance Report;
4. The pharmacy is randomly selected as part of the 25% of licensed pharmacies chosen for inspection; or
5. Five years have elapsed since the pharmacy was subjected to an on-site inspection.

8-005.04B On-site Inspection: When the Department determines, based upon the criteria specified in 175 NAC 8-005.04A, that the Pharmacy Quality Assurance Report does not fulfill the annual inspection requirement, a pharmacy inspector ~~must~~ will conduct an on on-site inspection to determine compliance with the Health Care Facilities Licensure Act and these regulations.

8-005.04C Results of Annual Inspections

8-005.04C1 When the Department finds that the pharmacy fully complies with the requirements of 175 NAC 8-003.01A item 3.m., 175 NAC 8-006 and 8-007, the Department will notify the pharmacy of its compliance within 30 days after the inspection.

8-005.04C2 When the Department finds that the licensee does not fully comply with the requirements of 175 NAC 8-003.01A item 3.m., 175 NAC 8-006 and 8-007, but the nature of the violations do not create an imminent danger of death or serious physical harm to the clients of the pharmacy and no direct or immediate adverse effect to the safety or security of the drugs, devices, and biologicals, the Department may send to the pharmacy a letter requesting that a statement of compliance be submitted. The letter ~~must~~ will include:

1. A description of each violation;
2. A request that the pharmacy submit a statement of compliance within 10 working days; and

3. A notice that the Department may take further steps if the statement of compliance is not submitted.

8-005.04C3 The statement of compliance submitted by a pharmacy must indicate any steps that have been or will be taken to correct each violation and the estimated time when each correction will be completed. Based on the statement of compliance, the Department will take one of the following actions:

1. If the pharmacy submits and implements a statement of compliance that indicates a good faith effort to correct the violations, the Department will notify the licensee of the acceptance of the statement of compliance; or
2. If the pharmacy fails to submit and implement a statement of compliance that indicates a good faith effort to correct the violations, the Department may initiate disciplinary action against the pharmacy license.

8-005.04C4 When the Department finds that the pharmacy fails to meet the requirements of 175 NAC 8-006 and 8-007, and the failure(s) would create an imminent danger of death or serious physical harm, the Department will revoke the pharmacy license.

8-005.05 Re-inspections

8-005.05A The Department may conduct re-inspections to determine if a pharmacy fully complies with the requirements of 175 NAC 8-006 and 8-007. ~~The reinspection must occur within 90 days of the first inspection, or sooner as requested by the licensee. The re-inspection may occur after the Department:~~ Re-inspection may consist of an on-site inspection or a review of documentation requested by the Department. Re-inspection occurs:

1. After the Department has issued a provisional license;
2. Before a provisional license is converted to a regular license;
3. After the Department has imposed disciplinary action;
4. Before a disciplinary action is modified or terminated; or
5. After the Department receives a statement of compliance for cited violations.

~~1. Receives a statement of compliance;~~
~~2. Has imposed disciplinary action; or~~
~~3. Has issued a provisional license.~~

8-005.05B Following a re-inspection, the Department may:

1. Convert a provisional license to a regular license;
2. Affirm that the provisional license is to remain effective; ~~or~~
3. Modify a disciplinary action in accordance with 175 NAC 8-008.02; or
4. Grant full reinstatement of the license.

8-005.06 Compliance Inspections ~~for Cause~~: The Department may~~,~~ ~~inspect a pharmacy to determine violations when any one or more of the following conditions or circumstances occur:~~ following the initial licensure of a pharmacy, conduct an unannounced on-site inspection at any time it deems necessary to determine compliance with 174 NAC 8-006 and 8-007. The inspection may occur based on random selection or focused selection.

8-005.06A Random Selection: Each year the Department may inspect up to 25% of the pharmacies based on a random selection of pharmacies.

8-005.06B Focused Selection: The Department may inspect a pharmacy when the Department is informed of one or more of the following:

1. An accident or natural disaster resulting in damage to the physical plant; or interruption of utility services which could result in adverse effects to the potency, efficacy, safety or security of the drugs, devices and biologicals;
2. A complaint alleging violation of the Health Care Facility Licensure Act or these regulations;
3. A complaint that raises concern about the maintenance, operation, or management of the pharmacy;
4. Financial instability of the licensee or of the licensee's parent company;
5. Change of: scope or type of services offered, management or location;
6. Failure to submit a Pharmacy Quality Assurance Report within 30 days of the due date;
7. Submitting incomplete or questionable answers on the Pharmacy Quality Assurance Report;
8. Any other event that raises concerns about the maintenance, operation, or management of the pharmacy.

8-006 STANDARDS FOR THE OPERATION OF A PHARMACY: The pharmacy must operate in accordance with the services as specified on the application for a pharmacy license or amendments thereto.

8-006.01 Staffing Requirements: Each pharmacy must maintain a sufficient number of staff with the qualifications, training, and skills necessary to meet patient needs. The pharmacy must ensure that the staff hired meets the following requirements:

8-006.01A Pharmacists hired by the pharmacy must have a pharmacist license on active status in accordance with 172 NAC 128.

8-006.01A1 A pharmacy must not coerce or attempt to coerce a pharmacist:

1. To dispense a prescription drug or device against the professional judgment of the pharmacist or as ordered by the prescribing practitioner;
2. To enter into a delegating dispensing agreement; or

3. To supervise any pharmacy technician for any purpose or in any manner contrary to the professional judgment of the pharmacist.

8-006.01B The pharmacy must have a pharmacist-in-charge and must ensure that the pharmacist-in-charge has the qualifications, training, and skills necessary to meet the requirements according to these regulations.

8-006.01C The pharmacy may employ pharmacist interns who must practice in accordance with 172 NAC 128-011.

8-006.01D The pharmacy may employ pharmacy technicians. Prior to the use of pharmacy technicians in a pharmacy, a copy of the pharmacy's written control procedures and guidelines must be submitted to the Department and these guidelines must be approved by the Board. The original, approved, written control procedures and guidelines and any approved amendments must be retained at the pharmacy. The written control procedures and guidelines, for the use of pharmacy technicians must contain the following information:

1. Name, street address, and telephone number of the pharmacy;
2. Name and Nebraska license number of the pharmacist-in-charge;
3. Means used by the pharmacy to determine that pharmacy technicians are at least 18 years of age;
4. Means used by the pharmacy to determine that pharmacy technicians have met the educational requirements of a high school diploma or G.E.D.;
5. Means used by the pharmacy to determine that pharmacy technicians have never been convicted of any drug-related misdemeanor or felony;
6. Means used by the pharmacy to provide training, on-site in the pharmacy, by a pharmacist, within the first month of employment of a pharmacy technician, on all components required by law;
7. Means used to document training of pharmacy technicians;
8. Means used by the pharmacy to confirm that pharmacy technicians have achieved a basic level of competency following training;
9. Maximum ratio of pharmacy technicians to one pharmacist working in the pharmacy at any time;
10. Method used by the pharmacy to supervise pharmacy technicians;
11. Tasks and functions which pharmacy technicians are allowed to perform in the pharmacy;
12. Method used by the pharmacy to assure that pharmacy technicians do NOT perform any task or function, which requires professional judgement;
13. Method of documentation used by the pharmacy to show that all drugs, devices, or biologicals dispensed with the assistance of a pharmacy technician conform to the order that authorized the drug, device, or biological to be dispensed;
14. Method of documentation used by the pharmacy to show that all acts, tasks and functions performed by pharmacy technicians are verified by a pharmacist as being accurate and complete;

15. Method used to identify pharmacy technicians while on duty; and
16. A notarized, signed statement from the pharmacist-in-charge verifying that all information in the application is correct.

8-006.02 Storage Requirements

8-006.02A The pharmacy must provide equipment for the storage of drugs, devices, and biologicals at the proper temperature:

1. Drugs, devices, or biologicals requiring refrigeration must be stored between 36 and 46 degrees Fahrenheit.
2. Drugs, devices, or biologicals requiring a freezer must be stored between -4 and 14 degrees Fahrenheit.
3. Drugs, devices, or biologicals requiring storage in a cool place must be stored between 46 and 59 degrees Fahrenheit, or under refrigeration, between 36 and 46 degrees Fahrenheit, unless otherwise specified.
4. Drugs, devices, or biologicals requiring storage at controlled room temperature must be stored between 59 and 86 degrees Fahrenheit.
5. Other labeled storage instruction for drugs, devices, or biologicals must be followed.

8-006.02B Drugs, devices, and biologicals stored in a refrigerator must be kept in a separate compartment from food.

8-006.02C The prescription inventory and prescription records of the pharmacy must be maintained in a secure location when there is no pharmacist on the premises. Loss of prescription inventory or prescription records due to theft or any other cause resulting from failure to secure the inventory or records are grounds for disciplinary action.

8-006.02D The pharmacy must not have in its dispensable inventory any drug, device, or biological which is misbranded or adulterated.

8-006.03 Record Keeping Requirements

8-006.03A All pharmacies must maintain the following records:

1. All pharmacies which use electronic record keeping systems ~~computerized or electromagnetic record keeping~~ must comply with the non-inventory record keeping requirements set out in Title 21 of the Code of Federal Regulations, Part 1304 and Part 1306, which are attached to these regulations and incorporated by this reference.
2. All pharmacies, which use a central record keeping system, must comply with all record keeping requirements set out in Title 21 of the Code of Federal Regulations, Part 1304, which are attached to these regulations and incorporated by this reference.

3. All pharmacies, which handle controlled substances, must keep complete and accurate records of receipt and disposition of all controlled substances accepted into inventory.
4. All pharmacies must keep accurate and complete records of dispensed drugs, devices, and biologicals returned to the dispensing pharmacy for immediate destruction by a pharmacist.
5. Both pharmacies involved in central filling must keep complete and accurate records of the receipt and disposition of drugs, devices, or biologicals, including but not limited to:

    a. Name of the pharmacist filling or refilling the prescription;
    b. Name of the pharmacy filling or refilling the prescription; and
    c. Name of the pharmacy that dispensed the prescription.

6. Any record, which contains privileged and confidential patient information, must be stored, secured, and disposed of in a manner that ensures confidentiality.
7. A copy of the documents used to determine the qualifications of a pharmacy technician as required in 175 NAC 8-006.01D items 3-5.

8-006.03A1 Prescription Files

1. Original ~~H~~hard copies of all dispensed prescriptions must be filed, in numeric order, in a three-file system as follows:

    a One file for controlled substance prescriptions in Schedule II;
    b. One file for controlled substance prescriptions in Schedules III, IV, and V; and
    c. One file for all other dispensed prescriptions.

2. Original ~~H~~hard copies of all dispensed prescriptions must include the following information:

    a. All information required for prescriptions as set forth in 175 NAC 8-006.04B;
    b. Prescription serial number;
    c. Date of initial filling;
    d. Quantity dispensed;
    e. If an emergency verbal Schedule II controlled substance prescription, “authorization for emergency dispensing” must appear on the face of the prescription; and
    f. If a Schedule II controlled substance prescription, the pharmacist or practitioner filling the prescription must write the date of filling and his/her own signature on the face of the prescription.

3. Original ~~H~~hard copies of all prescriptions dispensed must be maintained by the pharmacy for five years from the date of dispensing.

8-006.04 Dispensing Requirements

8-006.04A An automatic or vending machine, as found in Neb. Rev. Stat. § 71-1,147.15, is a mechanical device or process which does not have a pharmacist verifying the final product prior to presentation to the patient or caregiver. These regulations do not prohibit the use of mechanized counting machines, robotics, or other mechanical devices in the process of filling prescriptions. These regulations prohibit the use of these machines when there is no verification by a pharmacist.

8-006.04A1 When a pharmacy utilizes an automatic counting machine to assist a pharmacist in dispensing drugs documentation as to type of equipment, serial numbers, and policies and procedures for system operation must be maintained on-site in the Pharmacy for review by the Board of Pharmacy. Systematic documentation must be established to assure:

1. All controlled substances dispensed using this system are accounted for;
2. Drugs are maintained in a clean and sanitary environment and stored in accordance with current USP standards and in accordance with manufacturer labeling;
3. Drug dispensed are tracked by lot number and expiration date; and
4. Cassettes used in the counting machine, if any, are labeled with the following:

    a. Name of drug;
    b. Strength of the drug, if applicable;
    c. Dosage form of the drug; and
    d. The lesser of manufacturer's expiration date or expiration date of one year from transfer of drug to cassette

8-006.04A2 Pharmacies must maintain records with complete and accurate information of the following:

1. Date of transfer of the drug from the original container to the cassette;
2. Drug name, strength, dosage form, and quantity;
3. Manufacturer, distributor, or packager name;
4. Manufacturer, distributor, or packager lot number;
5. Manufacturer, distributor, or packager expiration date; and
6. Name and signature of person performing the transfer.

a. If the person loading the cassette is not a pharmacist, the responsible pharmacist must co-sign the records, verifying all drug transfer information is complete and accurate; and
b. If the drug being transferred is a controlled substance, two signatures must appear in the records verifying the transfer.

7. Verification that the central delivery chute and drug cassettes are kept in a clean manner according to manufacturer's recommendations and the method and substances used to clean these items; and
8. Quarterly documentation, which verifies actual count, by a pharmacist, against the machine for controlled substances dispensed from the cassettes in the quantity most commonly dispensed.

8-006.04A3 The expiration date for drugs transferred to cassettes must be the expiration date as determined by the manufacturer/distributor or a maximum of one year from the date of transfer, whichever is shorter. In the event that a cassette holds products containing drugs reflecting different lot numbers and expiration dates, the shortest expiration date will apply.

8-006.04A4 In the event of a FDA or State ordered Class I or Class II recall, all affected drugs must be recalled and removed from commerce. In the event that a cassette holds products from multiple lot numbers, all dosage units remaining in the container must be removed from commerce.

8-006.04A5 When specially calibrated cassettes are used, any changes occurring in the drug strength, or the drug manufacturer, distributor, or packager will require the acquisition of a new calibrated cassette or die from the manufacturer or distributor of the automatic counting machine.

8-006.04A6 Schedule II controlled substances cannot be transferred into or dispensed from automatic counting machines.

8-006.04B A prescription must contain the following information prior to being filled at a pharmacy:

1. Patient's name or if the patient is non-human, the name of the owner and species of the animal;
2. Name of the drug, device, or biological;
3. Strength of the drug or biological, if applicable;
4. Dosage form of the drug or biological, if applicable;
5. Quantity of drug, device, or biological prescribed;
6. Directions for use;
7. Date of issuance;
8. Prescriber's name and the name of the supervising or collaborating physician, when applicable;
9. Number of authorized refills; and

a. When the refill designation on the prescription is prn or Pro re nata, such designation, unless otherwise limited, means:

(1) If a prescription for a controlled substance in Schedules III-V, refill five times in the six months from the date of issuance, or
(2) If a prescription for a non-controlled drug, device or biological, refill for 12 months from the date of issuance.
(3) Controlled Substances in Schedule II cannot be refilled and a refill designation on a prescription for a controlled substance in Schedule II has no meaning.

10. If the prescription is for a controlled substance, the following additional information is required to be on the prescription:

a. Patient's address,
b. Prescriber's address, and
c. Prescriber's D.E.A. registration number.

8-006.04C Unit-Dose is a Packaging System

1. That contains individual sealed doses of a drug;
2. That may or may not attach the sealed doses to each other by placement in a card or other container;
3. Where the container may not contain doses for a period of greater than 14 days; and
4. That is non-reusable.

8-006.04D Unit-Dose Containers: Unit-dose containers returned to the dispensing pharmacy, from a long term care facility, for credit, must have a lot number and expiration date/calculated expiration date.

1. The calculated expiration date is used when the drug has been repackaged by the pharmacist into a unit-dose packaging system and is 25% of the remaining time between the date of repackaging and the manufacturer's or distributor's expiration date or six months from the date of packaging, whichever is less.
2. Lot number is the lot number assigned by the manufacturer, distributor, or packager.

8-006.04E In order for a pharmacy to accept the return of tablets or capsules from a long term care facility, these tablets and capsules must be packaged in a unit-dose container meeting the following requirements:

1. Unit-dose containers must meet the Class A or Class B guidelines for single-unit containers and unit-dose containers for capsules and tablets as set forth by the United States Pharmacopoeia.

2. Manufacturers, distributors or pharmacists wishing to use a unit-dose packaging system must present certified, scientific data demonstrating compliance with the Class A or Class B guidelines for moisture permeability as required by the United States Pharmacopoeia.

3. A new certificate of moisture impermeability is required when changes are made in the product. These changes may include, but are not limited to changes in:

    a. Adhesives;
    b. Plastics; or
    c. Cardboard formulation.

4. Only containers, which meet the following tamper-evident requirements and are approved by the Board, are considered to be returnable unit-dose containers:

    a. The package has an indicator or barrier to entry which, if breached or missing, can reasonably be expected to provide visible evidence to the health care practitioner that tampering has occurred.
    b. To reduce the likelihood of substitution of a tamper-evident feature after tampering, the indicator or barrier to entry is required to be distinctive by design or by the use of an identifying characteristic. “Distinctive by design” means that the packaging cannot be duplicated or replaced with readily available materials or through commonly available processes.
    c. A tamper-evident package may involve an immediate-container and closure system or a secondary-container or carton system or any combination of systems intended to provide a visual indication of package integrity.
    d. The tamper-evident feature must be designed to be and must remain intact when handled in a reasonable manner during dispensing to and storage at a long-term care facility.
    e. The tamper-evident feature is destroyed or rendered useless after the container is opened.

5. The return to the pharmacy of controlled substances, halved tablets, other broken dosage forms, and extemporaneously compounded tablets and capsules is prohibited.

8-006.04F Prescription Label: The pharmacy must provide equipment that allows for a legible prescription label to be affixed to the container prior to dispensing a drug, device or biological. The prescription label must contain the following information:

1. Name, address, and telephone number of the dispensing pharmacy and the central filling pharmacy, if central fill is used;
2. Serial number of the prescription;
3. Name of the drug, device, or biological, unless instructed to omit by the prescriber;
4. Strength of the drug or biological, if applicable;
5. Directions for use;
6. Quantity of drug, device, or biological in the container; except for unit-dose containers;
7. Any cautionary statements contained in the prescription;
8. Name of the patient or if the patient is non-human, the name of the owner and species of the animal;
9. Name of the prescriber,

    a. If prescribed by a physician assistant, both the name of the physician assistant and the name of the supervising physician must appear on the label. (Neb. Rev. Stat. § 71-1,107.30);

10. Dosage form of the drug or biological if applicable; and
11. Date of filling.

8-006.04G Prescription Labels for Multi-Drug Containers: The pharmacy may allow for the dispensing of more than one drug, device or biological in the same container only when:

1. Such container is prepackaged by the manufacturer, packager, or distributor and shipped directly to the pharmacy in this manner; or
2. Each drug or biological product is individually wrapped or hermetically sealed by either the pharmacist, dispensing medical practitioner, manufacturer, packager, or distributor; or
3. The container does not accommodate greater than a 31-day supply of compatible dosage units and is labeled so as to identify each drug or biological in the container in addition to all information required in 175 NAC 8-006.04F.

8-006.04H Patient Counseling: The pharmacy must provide the necessary resources for patient counseling to occur, including but not limited to, sufficient time and space. The pharmacy must only allow a pharmacist or a pharmacist intern to provide patient counseling, except as provided in Neb. Rev. Stat. § 71-1,147.35.

8-006.04H1 A verbal offer to counsel must be provided to the:

1. Patient, or
2. Patient's caregiver.

8-006.04H2 Patient counseling must occur, unless one of the following is documented:

1. Drug, device, or biological is being administered by a health care professional credentialed by the Department to a resident of a hospital or a long term care facility;
2. Patient or caregiver refuses to be counseled;
3. Pharmacist, in his/her professional judgement, determines that counseling could harm or injure the patient; or
4. Prescriber designates "contact before counseling" or words of similar import on the prescription. In this instance, the pharmacist must contact the prescriber prior to counseling and may use his/her professional judgement regarding counseling following consultation with the prescriber.

8-006.04I Drug Product Selection: The employer or such employer's agent may not restrict a pharmacist from choosing to dispense, without the duly licensed prescriber's express authorization, a chemically equivalent and bioequivalent drug product in place of the drug product ordered or prescribed.

8-006.05 Controlled Substance Requirements: A pharmacy that dispenses controlled substances must meet the following storage and inventory requirements.

8-006.05A Controlled Substance Storage

8-006.05A1 The pharmacy must store Schedule II, III, IV, and V controlled substances:

1. In a locked cabinet; or
2. Distributed throughout the inventory of non-controlled substances in a manner, which will obstruct theft or diversion of the controlled substances.

8-006.05A2 The pharmacy must store all Schedule I controlled substances in a locked cabinet.

8-006.05B Controlled Substance Record Keeping

8-006.05B1 Each pharmacy registered with the D.E.A. to handle controlled substances must complete an initial inventory on the date that s/he first engages in controlled substances activities. The information to be included on this inventory includes:

1. Name, address, and D.E.A. registration number of the registrant;
2. Date and time the inventory was taken, or last prescription number filled prior to taking the inventory to use as a reference point;
3. Whether the inventory was conducted at the opening or closing of business, when applicable; and
4. Signature of the person or persons responsible for taking the inventory.

The original copy of the initial inventory must be maintained in the pharmacy, for five years.

8-006.05C Controlled Substance Inventory

8-006.05C1 Each pharmacy registered with the D.E.A. to handle controlled substances must complete a biennial inventory in odd numbered years within 24 months of the previous biennial inventory date. The information to be included on this inventory includes:

1. Name, address, and D.E.A. registration number of the registrant;
2. Date and time or last prescription number filled prior to the inventory being taken, for a reference point;
3. Whether the inventory was conducted at the opening or closing of business, when applicable and
4. Signature of the person or persons responsible for taking the inventory.

The original copy of the biennial inventory must be maintained in the pharmacy for five years.

8-006.05C2 Each pharmacy registered with the D.E.A. to handle controlled substances must complete a controlled substances inventory whenever there is a change in the pharmacist-in-charge. Such inventory must contain all information required in the biennial inventory and the original copy of this inventory must be maintained in the pharmacy for five years.

8-006.05C3 Each inventory of controlled substances must contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken.

8-006.05C4 A copy of the initial controlled substances inventory**,** biennial controlled substances inventory, or a controlled substances inventory taken pursuant to a change in the pharmacist-in-charge must be forwarded to the Department, within 30 days after completion.

8-006.05C5 When taking an inventory of controlled substances:

1. An exact count or measurement of all controlled substances listed in Schedule I or II must be made;
2. An estimated count or measurement of all controlled substances listed in Schedules III, IV, or V may be made if the container holds 1,000 or fewer tablets or capsules;
3. An exact count of all controlled substances listed in Schedules III, IV, or V must be made if the container holds greater than 1,000 tablets or capsules;
4. All controlled substances, which are damaged, defective, or impure, must be included in the inventory;

5. All controlled substances awaiting return or destruction must be included in the inventory;
6. All controlled substances used in compounding must be included in the inventory;
7. Schedule II controlled substances must be listed separately from controlled substances in Schedules III, IV, and V; and
8. The inventory must include the name and strength of each controlled substance, the finished form of the substance, and the number of units or volume of each controlled substance.
9. If a drug or device, that has not been previously controlled is placed into one of the controlled substance schedules, the drug or device must be inventoried as of the effective date of scheduling and this inventory should be stored with the biennial inventory records.
10. If a drug or device changes schedules or is de-scheduled, the drug or device must be inventoried as of the effective date of the change and this inventory should be stored with the biennial inventory records.

8-006.05C6 The owner of any stock of controlled substances listed in Neb. Rev. Stat. § 28-405, when the need for these substances ceases, may:

1. When the owner is a registrant:

   a. Transfer controlled substances listed in Schedule I or II to another registrant, but only on a D.E.A. Form-222 as required by Neb. Rev. Stat. § 28-413;
   b. Transfer controlled substances listed in Schedule III, IV, or V to another registrant, but only in accordance with subsection (4) of Neb. Rev. Stat. § 28-411;
   c. Maintain the controlled substances separate from inventory for destruction by a pharmacy inspector, by a reverse distributor, or by the federal D.E.A. to be documented on a D.E.A. Form-41 or on an equivalent form supplied by the Department; and
   d. Comply with the requirements for disposal of controlled substances set out in Title 21 of the Code of Federal Regulations, Part 1307.21 and Part 1307.22, which are attached to these regulations and incorporated by this reference.
   ~~e. Destroy liquid controlled substances, in opened containers which originally contained 50 milliliters or less, or compounded liquid controlled substances, within the facility, when witnessed and documented by two persons licensed to practice an healing art in accordance with subsection (4) of Neb. Rev. Stat. § 28-411;~~

2. When the owner is a patient:

   a. Present the controlled substance to a pharmacy for immediate destruction by two responsible parties acting on behalf of the patient, one of whom must be licensed to practice an healing art;
   b. Who is a resident of a long term care facility or hospital, the long term care facility or hospital must assure that these controlled substances are destroyed as follows:

      (1) If the controlled substance is listed in Schedule II or III of Neb. Rev. Stat. § 28-405, the destruction must be witnessed by an employee pharmacist or a consultant pharmacist and a member of the healing arts; or
      (2) If the controlled substance is listed in Schedule IV or V of Neb. Rev. Stat. § 28-405, the destruction must be witnessed by an employee pharmacist or a consultant pharmacist and another responsible adult.

3. Complete records of controlled substances destruction must be maintained by the pharmacy, hospital, or long term care facility for five years from the date of destruction.

8-006.05D Controlled Substance Dispensing Requirement for Emergency Situations: For the purpose of authorizing an emergency prescription of a controlled substance listed in Schedule II of Neb. Rev. Stat. § 28-405, the term emergency situation means those situations in which the prescriber determines:

1. That immediate administration of the controlled substance is necessary, for proper treatment of the intended ultimate user; and
2. That no appropriate alternative treatment is available, including administration of a drug which is not a controlled substance listed in Schedule II, and
3. That it is not reasonably possible for the prescriber to provide a signed, written prescription to be presented to the person dispensing the substance, prior to dispensing.

8-006.06 Radiopharmaceutical Requirements

8-006.06A In addition to the preceding requirements, any pharmacy providing radiopharmaceutical services must comply with the regulations set forth in Neb. Rev. Stat. §§ 71-3515.01 to 71-3515.02 and the regulations promulgated thereunder.

8-006.07 Disaster Preparedness and Management: The pharmacy must establish and implement disaster preparedness plans and procedures to protect the potency, efficacy, safety, and security of the drugs, devices, or biologicals in the pharmacy in instances of

natural (tornado, flood, etc.) or other disasters, disease outbreaks, interruption of utility services, or other similar situations. Such plans and procedures must address and delineate:

1. How the pharmacy will provide for the storage of drugs, devices, and biologicals at the proper temperature;
2. How the pharmacy will provide for the disposal of drugs, devices, and biologicals if the pharmacy determines their potency, efficacy, or safety has been adversely affected;
3. How the pharmacy will secure the drugs, devices, and biologicals from the public; and
4. How the pharmacy will maintain patient records and inventory records.

8-007 PHYSICAL PLANT STANDARDS

8-007.01 The pharmacy must provide the pharmacist access to all equipment, facilities, and utilities appropriate for the accurate, efficient, and safe provision of the services available in that pharmacy.

8-007.02 The pharmacy must maintain the prescription department, including shelving, counters, floor, inventory, fixtures, equipment, and utensils in a clean, orderly, and sanitary manner.

8-007.03 The pharmacy must provide the pharmacist access to all reference material appropriate for the accurate, efficient, and safe practice of pharmacy or any specialty practice of pharmacy in the facility. These references must be up to date, in either printed or electronic form, and available at all times while the pharmacist is practicing for that pharmacy.

8-008 DENIAL, REFUSAL TO RENEW, OR DISCIPLINARY ACTION

8-008.01 Grounds for Denial, Refusal to Renew or Disciplinary Action

8-008.01A The Department may deny or refuse to renew a pharmacy license for failure to meet the requirements for licensure, including:

1. Failing an inspection specified in 175 NAC 8-005;
2. Failing to meet a compliance assessment standard adopted under Neb. Rev. Stat. § 71-442 as specified in 175 NAC 8-005.04A;
3. Having had a license revoked within the two-year period preceding an application; or
4. Any of the grounds specified in 175 NAC 8-008.01B.

8-008.01B The Department may take disciplinary action against a provisional pharmacy license or a pharmacy license for any of the following grounds:

1. Violation of any of the provisions of the Health Care Facility Licensure Act, or these regulations;

2. Committing or permitting, aiding, or abetting the commission of any unlawful act;
3. Conduct or practices detrimental to the health or safety of a pharmacy patient or employee;
4. A report from an accreditation body or public agency sanctioning, modifying, terminating, or withdrawing the accreditation or certification of the health care facility or health care service;
5. Failure to allow an agent or employee of the Department of Health and Human Services, the Department of Health and Human Services Finance and Support, or the Department of Health and Human Services Regulation and Licensure access to the pharmacy for the purposes of inspection, investigation, or other information collection activities necessary to carry out the duties of these departments;
6. Discrimination or retaliation against a pharmacy patient or employee who has submitted a complaint or information to the Department of Health and Human Services, the Department of Health and Human Services Finance and Support, or the Department of Health and Human Services Regulation and Licensure;
7. Discrimination or retaliation against a pharmacy patient or employee who has presented a grievance or information to the office of the state long-term care ombudsman;
8. Failure to allow a state long-term care ombudsman or an ombudsman advocate access to the hospital for the purposes of investigation necessary to carry out the duties of the office of the state long-term care ombudsman as specified in 15 NAC 3;
9. Violation of the Emergency Box Drug Act;
10. Failure to file a report of payment or action taken due to a liability claim or an alleged violation, as required by Neb. Rev. Stat. § 71-168.02;
11. Violation of the Medication Aide Act;
12. Failure to file a report of suspected abuse or neglect as required by Neb. Rev. Stat. §§ 28-372 and 28-711; or
13. Failure to account for significant, substantial shortages or overages of controlled substances.

8-008.02 Procedures for Denial, Refusal to Renew, or Disciplinary Action

8-008.02A If the Department determines to deny, refuse renewal of, or take disciplinary action against a license, the Department will send a notice to the applicant or licensee, by certified mail to the last address shown on its records. The notice ~~must~~ will state the determination, including a specific description of the nature of the violation and the statute or regulation violated, and the type of disciplinary action pending.

8-008.02B The denial, refusal to renew, or disciplinary action ~~must~~ will become final 15 days after the mailing of the notice unless the applicant or licensee, within the 15-day period, makes a written request to the Director for an informal conference or an administrative hearing.

8-008.02C Informal Conference

1. At the request of the applicant or licensee, the Department will hold an informal conference within 30 days of the receipt of the request. The conference ~~must~~ will be held in person or by other means, at the request of the applicant or licensee. If the pending action is based on an inspection, the Department's representative at the conference ~~must~~ will not be the individual who did the inspection.
2. Within 20 working days of the conference, the Department representative will state in writing the specific reasons for affirming, modifying, or dismissing the notice. The representative will send a copy of the statement to the applicant or licensee by certified mail to the last address shown in the Department's records and a copy to the Director.
3. If the applicant or licensee successfully demonstrates at the informal conference that the deficiencies should not have been cited in the notice, the Department will remove the deficiencies from the notice and rescind any sanction imposed solely as a result of those cited deficiencies.
4. If the applicant or licensee contests the affirmed or modified notice, the applicant or licensee must submit a request for hearing in writing within five working days after receipt of the statement.

8-008.02D Administrative Hearing

1. When an applicant or a licensee contests the notice and request a hearing, the Department will hold a hearing in accordance with the Administrative Procedure Act (APA) and the Department's rules and regulations adopted and promulgated under the APA. Either party may subpoena witnesses, who must be allowed fees at the rate prescribed by Neb. Rev. Stat. §§ 33-139 and 33-139.01.
2. On the basis of evidence presented at the hearing, the Director will affirm, modify, or set aside the determination. The Director's decision ~~must~~ will:

    a. Be in writing;
    b. Be sent by registered or certified mail to the applicant or licensee; and
    c. Become final 30 days after mailing unless the applicant or licensee, within the 30-day period, appeals the decision.

3. An applicant or a licensee's appeal of the Director's decision will be in accordance with the APA.

8-008.03 Types of Disciplinary Action

8-008.03A The Department may impose any one or a combination of the following types of disciplinary action against the license of a pharmacy:

1. A fine not to exceed $10,000 per violation;
2. A prohibition on admissions or re-admissions, a limitation on enrollment, or a prohibition or limitation on the provision of care or treatment;
3. A period of probation not to exceed two years during which the facility or service may continue to operate under terms and conditions fixed by the order of probation;
4. A period of suspension not to exceed three years during which the facility or service may not operate; and
5. Revocation which is a permanent termination of the license. The licensee may not apply for a license for a minimum of two years after the effective date of the revocation.

8-008.03B In determining the type of disciplinary action to impose, the Department will consider:

1. The gravity of the violation, including the probability that death or serious physical or mental harm will result;
2. The severity of the actual or potential harm;
3. The extent to which the provisions of applicable statutes, rules, and regulations were violated;
4. The reasonableness of the diligence exercised by the pharmacy in identifying or correcting the violation;
5. Any previous violations committed by the pharmacy; and
6. The financial benefit to the facility of committing or continuing the violation.

8-008.03C If the licensee fails to correct a violation or to comply with a particular type of disciplinary action, the Department may take additional disciplinary action as described in 175 NAC 8-008.03A.

8-008.03D Temporary Suspension or Temporary Limitation: If the Department determines that patients of the pharmacy are in imminent danger of death or serious physical harm, the Director may:

1. Temporarily suspend or temporarily limit the pharmacy license, effective when the order is served upon the pharmacy. If the licensee is not involved in the daily operation of the pharmacy, the Department will mail a copy of the order to the licensee, or if the licensee is a corporation, to the corporation's registered agent; or
2. Order the temporary closure of the pharmacy pending further action by the Department.

The Department will simultaneously institute proceedings for revocation, suspension, or limitation of the license, and ~~must~~ will conduct an administrative hearing no later than ten days after the date of the temporary suspension or temporary limitation.

1. The Department will conduct the hearing in accordance with the Administrative Procedure Act (APA) and the Department's rules and regulations adopted and promulgated under the APA. Either party may subpoena witnesses, who must be allowed fees at the rate prescribed by Neb. Rev. Stat. §§ 33-139 and 33-139.01.

2. If a written request for continuance of the hearing is made by the licensee, the Department will grant a continuance, which may not exceed 30 days.

3. On the basis of evidence presented at the hearing, the Director ~~must~~ will:

   a. Order the revocation, suspension, or limitation of the license; or
   b. Set aside the temporary suspension or temporary limitation.

   If the Director does not reach a decision within 90 days of the date of the temporary suspension or temporary limitation, the temporary suspension or temporary limitation will expire.

4. Any appeal of the Department's decision after hearing must be in accordance with the APA.

8-008.04 Reinstatement from Disciplinary Probation, Suspension, and Re-licensure Following Revocation

8-008.04A Reinstatement at the End of Probation or Suspension

8-008.04A1 Reinstatement at the End of Probation: A license may be reinstated at the end of probation after the successful completion of an inspection, if the Department determines an inspection is warranted.

8-008.04A2 Reinstatement at the End of Suspension: A license may be reinstated at the end of suspension following:

1. Submission of an application to the Department for renewal that conforms to the requirements of 175 NAC 8-003.02;
2. Payment of the renewal fee as specified in 175 NAC 8-004.11; and
3. Successful completion of an inspection.

The Department will reinstate the license when it finds, based on an inspection as provided for in 175 NAC 8-005, that the pharmacy is in compliance with the operational and physical plant standards of 175 NAC 8-006 and 8-007.

8-008.04B Reinstatement Prior to Completion of Probation or Suspension

8-008.04B1 Reinstatement Prior to the Completion of Probation: A licensee may request reinstatement prior to the completion of probation and must meet the following conditions:

1. Submit a petition to the Department stating:

    a. The reasons why the license should be reinstated prior to the probation completion date; and
    b. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the probation; and

2. Successfully complete any inspection that the Department determines necessary.

8-008.04B2 Reinstatement Prior to Completion of Suspension: A licensee may request reinstatement prior to the completion of suspension and must meet the following conditions:

1. Submit a petition to the Department stating:
    a. The reasons why the license should be reinstated prior to the suspension completion date; and
    b. The corrective action taken to prevent recurrence of the violation(s) that served as the basis of the suspension;

2. Submit a written renewal application to the Department as specified in 175 NAC 8-003.02;
3. Pay the renewal fee as specified in 175 NAC 8-004.11; and
4. Successfully complete an inspection.

8-008.04B3 The Director ~~must~~ will consider the petition submitted and the results of any inspection or investigation conducted by the Department and:

a. Grant full reinstatement of the license;
b. Modify the probation or suspension; or
c. Deny the petition for reinstatement.

8-008.04B4 The Director's decision is final 30 days after mailing the decision to the licensee unless the licensee requests a hearing within the 30-day period. The requested hearing ~~must~~ will be held according to rules and regulations of the Department for administrative hearings in contested cases.

8-008.04C Re-Licensure after Revocation: A pharmacy license that has been revoked is not eligible for re-licensure until two years after the date of revocation.

8-008.04C1 A pharmacy seeking re-licensure must apply for an initial pharmacy license and meet the requirements for licensure in 175 NAC 8-003.01.

8-008.04C2 The Department will process the application for re-licensure in the same manner as specified in 175 NAC 8-003.01.